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	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
_	09/889,383	02/05/2002	Marco Thyes	0480-01211	2952
	26474 7590 01/12/2007 NOVAK DRUCE DELUCA & QUIGG, LLP			EXAMINER	
	1300 EYE STR	EET NW		OH, TAYLOR V	
	SUITE 1000 WEST TOWER WASHINGTON, DC 20005			., ART UNIT	PAPER NUMBER
				1625	
L	SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS 01/12/2007			PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Paper No(s)/Mail Date

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) L Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date. \_

6) Other:

Notice of Informal Patent Application

### Final Rejection

#### The Status of Claims

Claims 3-8 are pending.

Claims 3-8 have been rejected.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 3-8 under 35 U.S.C. 112, second paragraph, has been withdrawn due to applicants' convincing argument in the amendment.

## Claim Rejections-35 USC 103

1. Applicants' argument filed 10/23/06 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

<u>The rejection of Claims 3-8 under 35 U.S.C. 103(a) as being unpatentable</u> over Novack (US 3,649,628).

The rejection of Claims 3-8 under 35 U.S.C. 103(a) as being unpatentable over Novack (US 3,649,628) is maintained for the reasons of the record on 6/23/06.

### **Applicants' Argument**

- 2. Applicants argue the following issues:
  - 1. There is no suggestion for interchangeability between hydrochloric acid and other organic acids for the separation of the cyclohexane base from the reaction mixture;
  - 2. The prior art lacks any incentive to adjust the amount of the acid to that of 0.75 to 2 equivalents per mole of the cyclohexene base, along with a period of 0.5 to 2 hours at a temperature of from 50 to 100° C.

The applicants' argument have been noted, but these arguments are not persuasive.

First, with respect to the first argument, the Examiner has noted applicants' argument. However, the specification of the prior art does teach that the cyclohexene

base can be converted into medicinally acceptable acid addition salt by conventional methods; salts can be made by reacting the base and the desired acid; such acids do include hydrochloric acid and organic acids, such as acetic acid (see col. 5 ,lines 11-26). From these, it becomes obvious that hydrochloric acid and acetic acid are interchangeable in the process of making the corresponding salt form. Therefore, there is a suggestion. Thus, it would have been obvious to the skilled artisan in the art to be motivated to use the acetic acid instead of hydrochloric acid as an alternative during the process. This is because the skilled artisan in the art would expect such a modification to be feasible and successful to the process as guidance (see col. 5 ,lines 11-26) as shown in the prior art.

Second, with respect to the second argument, the Examiner has noted applicants' argument. However, the specification of the prior art does teach that the reaction temperature is allowed to raise to 90 to 95° C for 2 hours (see col. 6, lines 35-37), which is very similar to the reaction conditions in the claimed invention. In addition, the limitation of a process with respect to ranges of molar ratio ,pH, time and concentration does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. The molar ratio is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity in a chemical process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to control the molar ratio between the carboxylic acid and ethyl 2 –

dimethylamino-1-phenyl-3-cyclohexene-1-carboxylate by a routine experimentation in order to achieve optimum operation of the process.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone

Application/Control Number: 09/889,383

Art Unit: 1625

number for the organization where this application or proceeding is assigned is 571-273-8300.

Page 6

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Taylor Victor Oh, MSD, LAC

1/7/07

**Primary Examiner** 

Art Unit: 1625